FDA: Moving Forward with CLIA ‘88

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CLIA Categorization

- FDA's past history with CLIA '88
- Transition from CDC
- Present
  - Current process at the FDA
  - HCFA and CDC roles
- Impact on Manufacturers
- Impact on Laboratories
- Future

FDA's History

- CLIA regulations issued in 1992
- FDA assigned responsibility for complexity categorization
- Issued >900 categorizations
- Resources, funding issues
- Responsibility delegated to CDC in 1994

CLIA Transition

- Impetus for change
- Manufacturers
- Congress
- “Confusion and duplication of effort”
- CDC, HCFA, FDA consensus
- Interagency agreement 2/27/99
- HCFA, CDC, FDA = CLIA partners

Interaction with CDC

- Cross Training
  - Orientation started Feb 1999
  - Parallel reviews started May 1999
- Consultation continues

FDA's Preparation

- Began hiring scientific reviewers, medical officers in Fall 1999
- Dual challenge
  - FDA review
  - CLIA categorization review
- Training in a continuum

FDA Reviews

- Clinical laboratory and blood bank tests; commercially marketed
- Center for Devices and Radiological Health - clinical lab tests
- Center for Biologics Evaluation and Research - tests for blood screening e.g. HIV, HCV

Present: FDA's Role in CLIA

- January 31, 2000
- Responsibility for categorization of commercially marketed *in vitro* diagnostic test systems
- Division of Clinical Laboratory Devices I determines categorization as they review premarket submissions.

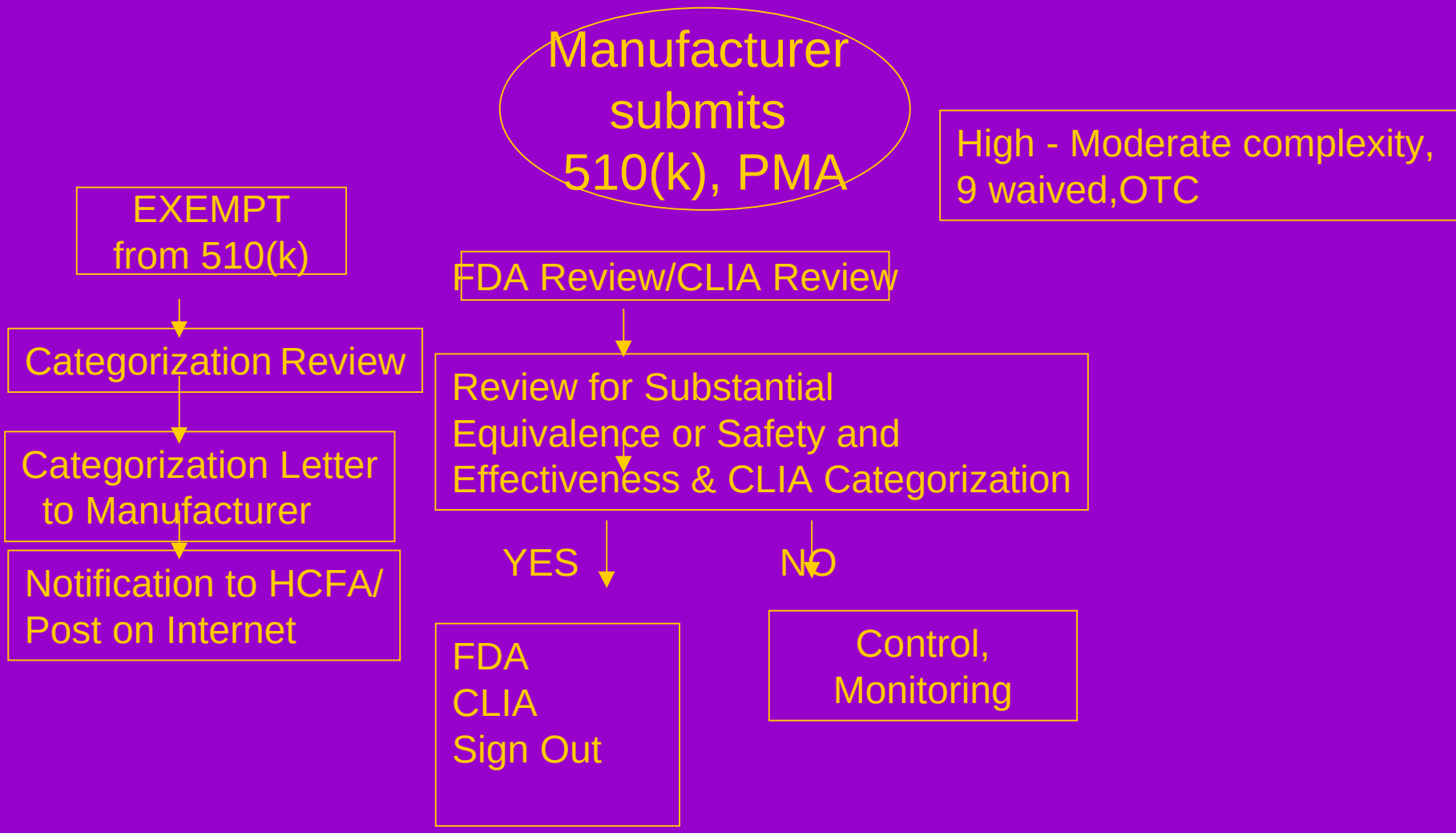
Sources of Information

- www.fda.gov/cdrh/clia.html
- Email account: CLIA@CDRH.FDA.GOV
- CLIA phone number: (301) 827-0496
- CLIA fax number: (301) 827-1401

Requests :

- Submitted to Document Mail Center
- Tracked in CDRH database
- Subject to internal timelines, to be determined

FDA Review & Categorization



FDA Review & Categorization

Manufacturer submits protocol cleared, approved

Waived Criteria 9/13/95

EXEMPT from 510(k)

Protocol approved

Studies, Data Application to FDA to Manufacturer

Protocol approved

Studies performed, data collected
Waiver Application submitted to FDA
Team Review/consultation w. CDC

YES

NO

Waiver

Reference Method, 90% rule

Team Review, Consultation with CDC

Categorization Notification Letter

- FDA’s document number is the key
- “K001111”
- complexity
- test system name
- analyte name

Supporting Cast

- HCFA - waived notification, package insert
- CDC - consultation particularly on waived applications
- Keep both apprised of new technology

Impact on Manufacturers

- Streamlined administrative process
- One stop agency for marketing and categorization
- Reviewer familiar with the products
- Categorization, no impediment to clearance or approval
- Improved turn around time, decision

Impact on Laboratories

- Improved turnaround time
- Access to FDA
- Releasable 510(k) database
- Releasable Premarket Approval Database
- Package insert

Releasable PMA Database

- Classification Name
- Generic Name
- Applicant
- PMA Number
- Supplement Number
- Trade Name
- Date Received

Releasable PMAs (cont...)

- Decision Date
- Product Code
- Advisory Committee
- Supplement Type
- Supplement Reason
- Expedited Review Granted (Y?N)
  - ***http://www.fda.gov/cdrh/pmapage.html***

510(k) Releasable Database

- Device Classification Name:
- Regulation Number:
- 510(k) Number:
- Device Name:
- Applicant:
- Contact:
- Product Code:

Releasable 510(k)s (cont...)

- Date Received:
- Decision Date:
- Decision:
- Classification Advisory Committee:
- Review Advisory Committee:
- Summary or Statement
  - **http://www.fda.gov/cdrh/510khome.html**

Progress Report

- >400 mod, high categorizations performed
- >50 waived

  -Over the counter (drugs of abuse)

  -prescription home use (prothrombin time)

  -waived by regulation - generic

  -relabeling of the above

  - “0” via waiver criteria

In the Pipeline

- Open public meeting late summer 2000
- Discuss proposed waiver criteria with stakeholders
- Options
- Repropose
- Finalize
- Negotiated rulemaking

Future

- What is your wish list?